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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
PAGE, BRENT T	

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1638	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/591,428	FROHBERG ET AL.	
	Examiner	Art Unit	
	BRENT PAGE	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 September 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17,19 and 21-39* is/are pending in the application.

4a) Of the above claim(s) *13-17,19,21-24,33 and 34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12,25-32 and 35-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 September 2006* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election with traverse of Group I and SEQ ID NO: 3 encoding SEQ ID NO: 4 in the reply filed on 09/15/2008 is acknowledged. The traversal is on the ground(s) that the technical feature linking the inventions is products and methods related to the OK1 protein and not a phosphoglucan gene or protein.

This is not persuasive because the phosphorylation of starch by the OK1 protein depends on prior phosphorylation by the R1 protein, and therefore art taught by Ritte et al is clearly related to the OK1 protein and falls under the category of "products and methods related to an OK1 protein" (see page 3 of response).

Applicants also urge that the R1 protein and OK1 protein are distinct.

This is not persuasive because for example claim 1, and indeed many claims of the instant claim set, are not limited to nucleic acids encoding the OK1 protein, but rather recite any genetic modification that increases the activity of the OK1 protein. Because the OK1 protein is only active when starch is phosphorylated by R1, an increase in the R1 protein, as taught by Ritte, would lead to an increase in activity of the OK1 protein, and therefore, meets the limitations of this particular feature of the invention. Regardless, as cited below, Kikuchi et al do teach a nucleic acid encoding the OK1 protein, and therefore the technical feature linking the inventions whether it is nucleic acid sequences encoding the OK1 protein, nucleic acid sequences increasing the activity of the OK1 protein, or phosphoglucan genes or proteins, are all considered not to be an advancement over the prior art as discussed in the restriction requirement mailed out on 06/13/2008 as well as the reasons stated above.

The requirement is still deemed proper and is therefore made FINAL.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. There are 9 embedded hyperlinks, 2 in paragraph 87 of the specification, 1 in paragraph 88, 3 in paragraph 398, 2 in paragraph 337, and 1 in paragraph 499 of the specification. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Drawings

New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because the drawing for Figure 1 has been omitted. Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

Claims 1-12, 25-32 and 35-39 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the overexpression of SEQ ID NO:3 for increasing activity in at least one OK1 protein in plant that also expresses glucan, water dikinase, does not reasonably provide enablement for any genetic modification of any gene that leads to an increase in activity of OK1 in any plant background, nor does

the specification reasonably provide enablement for any sequence that encodes any OK1 protein in any plant background. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims are drawn to a genetically modified plant cell of any species and of any genetic background that exhibits increased activity in at least one OK1 protein in comparison to corresponding wild type plant cells wherein the starch has been modified with an increased phosphate content as well as nucleic acids, vectors and host cells.

In contrast the specification only provides guidance for the expression of full-length nucleic acid sequences, in particular SEQ ID NO:3 which encodes SEQ ID NO:4, in a plant that also expresses glucan, water dikinase. The specification does not give guidance for the increase of expression of OK1 using any other nucleic acid sequences, of any other genes including any regulators such as a transcription factor, and do not give guidance as to what aspects of the exemplary embodiment are required and critical to the increase in activity of the said protein.

The modification of starch content and the increased activity of OK1 is not predictable in all plant backgrounds using any nucleic acid sequences as broadly claimed. In a study of starch phosphorylation and the effect of glucan, water dikinase (GWD) and the effect of phosphoglucan, water dikinase (PWD, also known as OK1) Hejazi et al (2008 The Plant Journal 55:323-334), disclose that phosphorylation of the starch by PWD requires the phosphorylation of the starch prior to that by GWD (see page 326, last paragraph for example). In a background where the R1 gene is null,

phosphorylation of the starch by OK1 (PWD) could not occur, and the starch could not be modified. Furthermore, the specification does not provide any guidance as to which sequences are required of the amino acid sequence to be considered an OK1 protein. For example, the specification mentions a phosphohistidine domain (page 14 of the instant specification), however, the R1 protein also comprises this domain, there is no other guidance as to what sequence requirements there are for functioning embodiments. Additionally, not all such enzymes are known and isolated. For example, in a study on the phosphorylation of starch, Ritte et al (2006 FEBS Letters 580:4872-4876) disclose that "In addition to GWD and PWD the existence of another putative starch phosphorylating dikinase (designated as AtGWD2) was predicted from the analysis of the Arabidopsis genome. AtGWD2 is not yet fully characterized but the remaining starch phosphorylation at C6 in *sex*1-3 and *sex*1-8 plants might be due to this isoenzyme". Since the phosphorylation of starch by OK1 requires GWD, and not all GWD proteins are characterized, as discussed above, it would be undue experimentation to evaluate all plant backgrounds and all GWD proteins and to determine whether or not the starch of the plant would be phosphorylated by OK1. Similarly, the lack of characterization of pathway means that it would be undue experimentation to isolated and evaluate all nucleic acids of the plant's genome that might affect the expression and/or activity of the OK1 gene and/or protein. Furthermore, because this pathway is not fully characterized and understood, it would likewise be undue experimentation to isolate and evaluate all sequences that might

encode an OK1 protein and determine whether or not starch is phosphorylated by it even in backgrounds that have fully functioning GWD proteins.

Given the state of the art and the disclosures by Hejazi et al and Ritte et al, it would be undue experimentation for one of skill in the art to isolate, identify and evaluate all nucleic acid sequences for their ability to increase the activity of an OK1 protein in genetically modified plant cells. It would also be undue experimentation for one of skill in the art to isolate, identify and evaluate all nucleic acid sequences to determine if they encode a functional OK1 protein as broadly claimed in a myriad of genetically modified plants, modified either by mutation or by transformation, by testing for an unspecified starch phosphate content and/or a modified phosphate distribution.

Claims 1-12, 25-32 and 35-39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to multitudes of sequences which function to either increase the activity of OK1 protein, or encode the OK1 protein.

In contrast, the specification only describes two full-length sequences, SEQ ID NO:3 and SEQ ID NO:1 which are known to encode OK1 from rice and Arabidopsis respectively. The specification does not provide working examples of any other sequences that encode OK1 or any other sequences that increase the activity of OK1. Furthermore, the specification does not describe the structures that would be required

for such functions. In the absence of working examples and literal description, Applicant is required to at least provide a description of the necessary structures that would be required for the claimed function to be in possession of the full scope of the claims. In claim 25 in particular, wherein the nucleic acid molecule comprises a nucleic acid molecule coding a protein that has an amino acid sequence with an identity of at least 60% with SEQ ID NO:4, or 60% identity with the nucleic acid of SEQ ID NO:3, the claims encompass nucleic acid sequences encoding amino acid sequences with anywhere from 1to 482 amino acid substitutions, deletions, or insertions in any combination over the entire length of the sequence, with no description of which nucleic acids or which amino acids may not be modified. The fragments, allelic variants and sequences that hybridize under unspecified stringencies are also broad claim language wherein the specification does not describe which sequences must be conserved in order for the sequence to be considered an OK1 protein or a protein that increases the activity of an OK1 protein.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." Id. Further, the court held that to adequately describe a claimed genus,

Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus." Id.

Finally, the court held:

> A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. Id.

See also MPEP section 2163, page 174 of chapter 2100 of the August 2005 version, column 1, bottom paragraph, where it is taught that

> [T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

See also Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ 2d 1016 at 1021, (Fed. Cir. 1991) where it is taught that a gene (which includes a promoter) is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence).

Given the claim breadth and lack of description as discussed above, the specification fails to provide an adequate written description of the genus of sequences as broadly claimed. Given the lack of written description of the claimed genus of sequences, any method of using them, such as transforming plant cells and plants therewith, and the resultant products including the claimed transformed plant cells and

plants containing the genus of sequences, would also be inadequately described. Accordingly, one skilled in the art would not have recognized Applicant to have been in possession of the claimed invention at the time of filing. See the Written Description Requirement guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 5, 2001/ Notices: pp. 1099-1111.

Claim Rejections - 35 USC § 102

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-2, 4-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Frohberg (US Patent 6521816) in light of Ritte et al (2006 FEBS Letters 580:4872-4876).

The claims are directed to a genetically modified plant cell which exhibits increased activity in at least one OK1 protein comprising at least one foreign nucleic acid molecule, wherein a modified starch is synthesized wherein the modified starch has a modified C-3 phosphate to C-6 phosphate ratio, wherein the plant is maize or wheat, propagation material from said plant, a harvestable part of said plant and a method of manufacturing a genetically modified plant.

Frohberg teaches the transformation of a host cell with an isolated nucleic acid that encodes and R1 protein, wherein the starch of the cell is modified (see claims 1, 2, 4-5, 8, 10, 11, 13-17, for example) in the C-3 phosphate to C-6 phosphate ratio and

wherein the OK1 protein is inherently increased in light of Ritte et al who teaches that the activity of PWD (OK1) is strictly dependent on phosphorylation of the starch by GWD (R1) and that GWD phosphorylated c-6 while OK1 phosphorylates c-3 (see page 4875 first paragraph under discussion, for example).

Claims 1-8, 10-12, 25-32, and 35-39 are rejected under 35 U.S.C. 102(e) as being anticipated by Kikuchi et al (US20060123505A1, filed May 29, 2003).

The claims are directed to a genetically modified plant cell which exhibits increased activity in at least one OK1 protein comprising at least one foreign nucleic acid molecule, wherein a modified starch is synthesized wherein the modified starch has a modified C-3 phosphate to C-6 phosphate ratio, wherein the plant is maize or wheat, propagation material from said plant, a harvestable part of said plant and a method of manufacturing a genetically modified plant, wherein the foreign nucleic acid encodes an OK1 protein from Arabidopsis or rice, has at least 60% identity to SEQ ID NO:3, and a host cell, vector, composition, plant and harvestable parts all comprising said foreign nucleic acid molecule.

Kikuchi et al teach the transformation of a host cell and regeneration of a plant with SEQ ID NO:22133 which is 99.5% identical to SEQ ID NO:3 and encodes the OK1 protein or PWD from rice, a vector comprising the sequence and plant parts therefrom, wherein that starch properties are inherent in the expression of the foreign nucleic acid (see claims 1-2, 5-6, 9, and 13-17, for example.

Double Patenting

Claim 12 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 12 of copending Application No. 10591540. Although the conflicting claims are not identical, they are not patentably distinct from each other because they claim the same method and the same method steps. The only difference is the starting material cells, but both claim a method of manufacturing a genetically modified plant comprising genetically modifying a plant cell wherein the genetic modification increases the activity of at least one OK1 protein.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRENT PAGE whose telephone number is (571)272-5914. The examiner can normally be reached on Monday-Friday 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571)-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brent T Page

/Russell Kallis/

Primary Examiner, Art Unit 1638